

Serial No.: 10/069,892
Docket No.: PHD99207

Amendment A

Remarks

Claims

Claims 1-8 are pending in the application.

Claims 4-6 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Van Wagenen *et al.* (US 4,784,486).

Claims 1-8 remain in the application unamended. Claims 4-6 have been amended. Claims 9 and 10 have been added.

THE VAN WAGENEN REFERENCE

Van Wagenen *et al.*, is directed to gas analysis and, more specifically, to systems for the simultaneous analysis of multiple gases by laser-induced Raman light scattering. See, Van Wagenen *et al.*, column 1, lines 7-10.

Van Wagenen *et al.* teaches that continuous breath-by-breath analysis of a patient's respiratory gases in the operating room is becoming increasingly important in improving patient safety during anesthesia. Respiratory and anesthetic gas monitoring, as well as the determination of specific cardiac and pulmonary functions which are based upon the uptake and production of specific tracer and respiratory gases, has reached a high standard of technological advancement with the development of sophisticated sensors, transducers and computers. Applications of respiratory gas and anesthetic agent monitoring include the measurement of oxygen consumption, carbon dioxide production, anesthetic agent uptake and the possibility of detecting anesthesia machine circuit disconnections and introduction of air emboli into the blood. See, Van Wagenen *et al.*, column 1, lines 14-33.

At column 17, lines 26-27, Van Wagenen *et al.*, goes on to teach that its primary interest is focused on analysis of respiratory and anesthetic agent gases. More specifically, Van Wagenen *et al.* teaches that in a preferred embodiment for the identification and quantitation of anesthetic agents and respiratory gases, eight multilayer dielectric filters 217 are used. Anesthetic agents halothane, enflurane, and isoflurane are detected by filters 217 having center wavelengths of 505.7 nm, 508.2 nm and 512.9 nm, respectively. Carbon dioxide, oxygen, nitrous oxid and nitrogen

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are quantitated by filters 217 having center wavelengths of 523.5 nm, 528.1 nm, 547.4 nm and 550.6 nm, respectively. See, Van Wagenen *et al.*, column 18, lines 10-19.

THE PRESENT APPLICATION

The present invention relates to poisoning effects during anesthesia. During anesthesia with one of the agents desflurane, isoflurane or enflurane, patients can accidentally become exposed to carbon monoxide, CO, thus leading to an inadvertent CO-poisoning of the patient. Usually, the accidental CO exposure goes undetected, because CO is not identified or measured by the commercially available medical gas monitors.

According to the invention, the CO concentration in a respiration gas is directly and/or indirectly measured in a substantially continuous monitoring process. An alarm is provided when the monitored concentration exceeds one or more given threshold values. Thus, for example, a timely warning can be issued so that the clinical personnel can replace the CO₂ absorber material before any harm will be done to the patient.

An indirect monitoring of the CO concentration in a respiration gas is applied by measuring a by-product of the anesthetic agent degradation process other than CO. For example, a by-product is selected which is absorbed in the body to a lower degree than CO and thus easier to detect than CO. The by-product is thus employed as an indicator for the presence of CO. Trifluoromethane, CHF₃, is an example of such an indicator.

The 35 U.S.C. § 112 Rejections

Claims 4-6 have been amended to remove the phrase "preferably" and the text associated therewith. Accordingly, Applicant respectfully submits that claims 4-6 meet the requirements of 35 U.S.C. § 112, second paragraph.

The 35 U.S.C. § 102(b) Rejections

Claim 1 is directed to a system (10) for avoiding poisoning effects during anesthesia, comprising: determining means (60, 70) for determining the quantitative amount of an anesthetic agent degradation product in an anesthetic gas mixture, and alarm means for providing an alarm when the determined quantitative amount of the

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anesthetic agent degradation product in the anesthetic gas mixture exceeds a given threshold.

Applicant respectfully asserts that Van Wagenen *et al.* does not teach or suggest all of the claim limitations of claim 1. As noted above, Van Wagenen *et al.* is directed to the identification and quantitation of anesthetic agents and respiratory gases, preferably, halothane, enflurane, and isoflurane (anesthetic agents) and carbon dioxide, oxygen, nitrous oxide and nitrogen. By contrast, the present invention relates to the identification of anesthetic agent degradation products (such as carbon monoxide and trifluoromethane.) Accordingly, Applicant respectfully asserts that Van Wagenen *et al.* does not teach or suggest determining means (60, 70) for determining the quantitative amount of an anesthetic agent degradation product in an anesthetic gas mixture, and alarm means for providing an alarm when the determined quantitative amount of the anesthetic agent degradation product in the anesthetic gas mixture exceeds a given threshold as set forth in claim 1.

In light of the foregoing, Applicant respectfully asserts that the rejection of claim 1 under 35 U.S.C. § 102(b) should be withdrawn and that claim 1 is patentable over the prior art of record.

Claim 2 is directed to the system (10) of claim 1, wherein the determining means (60, 70) comprises: measuring means (60) for measuring a Raman spectrum of the gas mixture, and a processing unit (70) for determining the quantitative amount of the anesthetic agent degradation product in the gas mixture by comparing the measured Raman spectrum with a reference spectrum of the anesthetic agent degradation product.

For reasons similar to those applied above to claim 1, Applicant respectfully asserts that Van Wagenen *et al.* does not teach or suggest a processing unit for determining the quantitative amount of the anesthetic agent degradation product in the gas mixture as set forth in claim 2. Accordingly, Applicant respectfully asserts that claim 2 is patentable over the prior art of record.

Claim 3 is directed to the system (10) of claim 1, wherein the anesthetic agent degradation product is carbon monoxide CO.

As with claims 1 and 2, Van Wagenen *et al.* is directed to the identification and quantitation of anesthetic agents and respiratory gases, preferably, halothane, enflurane, and isoflurane (anesthetic agents) and carbon dioxide, oxygen, nitrous

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oxide and nitrogen. By contrast, the present invention relates to the identification of anesthetic agent degradation products such as carbon monoxide as set forth in claim 3.

In light of the foregoing, Applicant respectfully asserts that claim 3 is patentable over the prior art of record.

Claim 4 is directed to the system (10) according to claim 1, wherein the anesthetic agent degradation product is trifluoromethane, CHF_3 , as an indicator for the presence of CO in the gas mixture.

Again, Van Wagenen *et al.* does not teach or suggest identifying anesthetic agent degradation products such as CHF_3 as set forth in claim 4. Further, Van Wagenen *et al.* does not reference desflurane. Thus, the assertion in the Office Action that CHF_3 is taught inherently by Van Wagenen *et al.* is not supported.

In light of the foregoing, Applicant respectfully asserts that claim 4 is patentable over the prior art of record.

Claim 5, is directed to a system (10) for avoiding CO poisoning effects during anesthesia caused by anesthetic agent degradation products in a gas mixture such as a respiration gas, comprising: means (60) for measuring a Raman spectrum of the gas mixture, a processing unit (70) for determining the quantitative amount of at least one of the anesthetic agent degradation products in the gas mixture by comparing the measured Raman spectrum with a reference spectrum of the at least one anesthetic agent degradation products, and means for providing an alarm when the determined quantitative amount of the anesthetic agent degradation product in the gas mixture exceeds a given threshold.

The reasons for the patentability of claim 1 can be applied *mutatis mutandis* to claim 5. Accordingly, Applicant respectfully asserts that claim 5 is patentable over the prior art of record.

Claim 6 is directed to a method for avoiding poisoning effects during anesthesia, comprising the steps of: (a) determining the quantitative amount of an anesthetic agent degradation product in an anesthetic gas mixture, and (b) providing an alarm when the determined quantitative amount of the anesthetic agent degradation product in the anesthetic gas mixture exceeds a given threshold.

The reasons for the patentability of claim 1 can be applied *mutatis mutandis* to claim 6. Accordingly, Applicant respectfully asserts that claim 6 is patentable over the prior art of record.

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Claim 7 depends from claim 6. For at least the reasons set forth above in connection with the patentability of claim 6, Applicant respectfully submits that claim 7 is patentable over the prior art of record.

Claim 8 is directed to the use of a Raman spectrometer (60, 70) for determining the quantitative amount of an anesthetic agent degradation product in a gas mixture.

The reasons for the patentability of claim 1 can be applied *mutatis mutandis* to claim 8. Accordingly, Applicant respectfully asserts that claim 8 is patentable over the prior art of record.

New **Claim 9** is directed to a method for avoiding poisoning effects during anesthesia accordingly to claim 6 wherein the anesthetic agent degradation product comprises at least one of carbon monoxide and trifluoromethane.

For at least the reasons set forth above in connection with the patentability of claim 6, Applicant submits that claim 9 is patentable over the prior art of record. It is further submitted that new claim 9 does not add additional matter which would require a further search.

New **Claim 10** is directed to a system according to claim 5 wherein the anesthetic agent degradation product comprises at least one of carbon monoxide and trifluoromethane

For at least the reasons set forth above in connection with the patentability of claim 5, Applicant submits that claim 10 is patentable over the prior art of record. It is further submitted that new claim 10 does not add additional matter which would require a further search.

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Conclusion

Applicant submit that claims 1-10 distinguish patentably and non-obviously over the prior art of record and are in condition for allowance. An early indication of allowability is earnestly solicited.

If any fees are due in connection with this application, authorization to charge deposit account 14-1270 for such fees is hereby provided.

Respectfully submitted,



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